WHAT IS CLAIMED IS

1. An aqueous suspension composition of water insoluble or poorly soluble biologically active substance together with at least one surface modifier and a pharmaceutically acceptable, water soluble polyhdroxy thermoprotecting agent, the ratio of active substance to surface modifier and thermoprotecting agent selected to provide particle size stability during and after terminal steam sterilization, provided that the particle size is not more than an about two-fold increase in the volume weighted mean particle size of the particulate aqueous suspension subsequent to terminal steam sterilization.

2. An aqueous suspension composition of water insoluble or poorly soluble biologically active substance together with at least one surface modifier and a pharmaceutically acceptable, water soluble polyhdroxy thermoprotecting agent, the ratio of active substance to surface modifier and thermoprotecting agent selected to provide particle size stability during and after terminal steam sterilization, provided that the particle size is not more than an about two-fold increase in the volume weighted mean particle size of the particulate aqueous suspension subsequent to terminal steam sterilization, wherein the composition is substantially completely devoid of surfactants that require elevation of their cloud point temperature by addition of a cloud point modifier for further stabilization and substantially devoid of surfactant additives which cause destabilization of the formulation.

3. The composition of claim 1 wherein the pH of the suspension before terminal steam sterilization is between about 5 to about 9 provided the pH value prior to terminal steam sterilization is selected such that the chemical stability of the suspension components is maintained during and after the terminal steam sterilization step.

4. The composition of claim 1 wherein the composition also includes an amount of non-surfactant additives such that the composition attains a suitable osmotic pressure for safe parenteral administration.

5. The composition of claim 1 wherein the composition also includes an amount of non-surfactant additive such that, on diluting the formulation with pharmaceutically acceptable diluent suitable for parenteral administration to a pharmaceutically acceptable concentration for parenteral administration, a suitable osmotic pressure of the diluted suspension results.

6. The composition of claim 1 wherein the thermoprotecting agent is a pharmaceutically acceptable water soluble polyhydroxy compound selected from the group consisting of trehalose, lactose, dextrose, sorbitol, dextran, trehalose and mannitol.

7. The composition of claim 1 wherein one or more of the surface modifiers are natural phospholipids or synthetic phospholipids.

8. The composition of claim 7 wherein the surfacemodifier is an egg phospholipid or soy phospholipid.

9. The composition of claim 1 wherein the amount of the surface modifier provides drug to surface modifier ratio of up to 5:1.

10. The composition of claim 1 wherein the amount of surface modifier is in the range from about 0.2% w/w to about 5.0% w/w.

11. The composition of claim 1 wherein the composition also contains pharmaceutical excipients for ophthalmic, peroral, or transdermal administration of the water insoluble or poorly soluble active drug substance.

12. The composition of claim 1 wherein the active substance is an antifungal agent

13. The composition of claim 12 wherein the active substance is itraconazole.

14. The composition of claim 1 wherein the active substance is an immuno-suppressive drug.

15. The composition of claim 14 wherein the active substance is a cyclosporin

16. The composition of claim 1 wherein the active drug is a sterol

17. The composition of claim 16 wherein the active drug is a alfaxalone

18. A lyophilized or spray dried powder prepared from the composition of claim 1.

19. A composition according to claim 1 wherein the water-insoluble or poorly water-soluble active drug substance is at a concentration suitable for either immediate release or sustained release delivery of the drug by parenteral administration.

20. The composition of claim 19 wherein the parenteral administration is intramuscular, or subcutaneous administration.